K010026

JUN 2 1 2001

SPECIAL 510(K) SUMMARY
FOR
Biosphere Medical, Inc.
BioGold™ Microsphere

1. SPONSOR

Biosphere Medical™, Inc
1050 Hingham Street
Rockland, MA 02370
Telephone: 781-681-7900
Fax: 781-681-5093
E-mail www.biospheremed.com

Company Contact

John D. Bonasera
Director of Regulatory and Quality Affairs
Phone: 781-681-7985
Fax 781-681-5093
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2. DEVICE NAME

Proprietary Name: EmboGold™ Microsphere
Common/Usual Name: Artificial emboli
Classification Name: Artificial Embolization Device (21 CFR 882.5950 & 21 CFR 870.3300)

3. PREDICATE DEVICE

Manufacturer Biosphere Medical, Inc.
Device: Embosphere® Microspheres
510(k): k991549
Date: April 26, 2000

4. DEVICE DESCRIPTION

EmboGold™ Microspheres are a colored version of Embosphere® Microspheres, a device which the subject of a cleared 510(k). The two products are identical in all aspects except EmboGold™ Microspheres are colored by the addition of metallic gold.

Embosphere® Microspheres received 510(k) clearance for distribution on April 26, 2000. Microspheres are infused into the arterial blood supply through a catheter and create artificial embolism to treat hypervascularized tumors and arteriovenous malformations..

Biosphere Medical EmboGold™ Microspheres and Embosphere® Microspheres are small, flexible, hydrophilic, biocompatible spheres made of acrylic polymer and porcine derived gelatin. These are packaged in 0.9% saline and are sterile and non pyrogenic.

Microspheres are calibrated to produce a controlled size range of particles. Various sizes are available to allow the physician to select Embospheres® and Embogold™ Microspheres that are suitably matched to the diameter of the vessel which has been targeted for embolization. EmboGold™ Microspheres will be offered in the same sizes ranges as Embosphere® Microspheres:

40-120μ
100-300μ
300-500μ
500-700μ
700-900μ
900-1200μ

Embosphere® Microspheres can be described as clear or slightly whitish in color. EmboGold™ Microspheres are identical to the current Embosphere® Microspheres with the exception that they are purple/red in color for improved visibility in handling and preparation by the physician. The contents of 510(k)991549 Embosphere® Microspheres, is directly applicable to EmboGold™ Microspheres. Metallic gold is added to the Embosphere® Microsphere to produce the color of Embogold™ Microspheres.

5. INTENDED USE

EmboGold™ Microspheres are indicated for embolization of hypervascularized tumors and arteriovenous malformations

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The method of application for EmboGold™ Microspheres and the predicate device Embosphere Microspheres is the same. These are identical devices, with the exception of the color of EmboGold™ Microspheres which has no impact on the technological characteristics or any other aspect of the predicate device Embosphere® Microsphere. EmboGold™ Microspheres are in fact colored Embosphere® Microspheres.

7. PERFORMANCE TESTING

Toxicological data and a Toxicological Assessment demonstrate that EmboGold™ Microspheres are biocompatible and safe for use. This addresses the change to Embosphere® Microspheres by the addition of gold to provide color and result in EmboGold™ Microspheres. There is no change in effectiveness or use of the product because of the coloring change to the microspheres. The color is intended to make device more visible to the physician when preparing and injecting the EmboGold™ Microspheres in a syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2002

Ms. Sharon Timberlake
Manager, Clinical and Regulatory Affairs
Biosphere Medical
1050 Hingham Street
Rockland, MA 02370

Re: K010026
Trade/Device Name: EmboGold Microsphere
Regulation Number: 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: May 21, 2002
Received: May 23, 2002

Dear Ms. Timberlake:

This letter corrects our substantially equivalent letter of June 21, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN) K010026

DEVICE NAME: EmboGold™ Microspheres (Biosphere Medical, Inc)

INDICATIONS FOR USE:

EmboGold™ Microspheres are indicated to be used for embolization of hypervascularized tumors and arteriovenous malformations.

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010026

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter-Use
(Optional Format 1-2-96)

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010026